# **HUMAN SERVICES DEPARTMENT[441]**

## **Notice of Intended Action**

Proposing rule making related to pharmacy protocols for naloxone, nicotine replacement therapy, and vaccines and providing an opportunity for public comment

The Human Services Department hereby proposes to amend Chapter 77, "Conditions of Participation for Providers of Medical and Remedial Care," Chapter 78, "Amount, Duration and Scope of Medical and Remedial Services," and Chapter 79, "Other Policies Relating to Providers of Medical and Remedial Care," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 249A.4.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 249A.4.

# Purpose and Summary

The Iowa Board of Pharmacy, in collaboration with the Iowa Department of Public Health, developed statewide protocols for pharmacists ordering and dispensing naloxone and nicotine replacement therapy (NRT) tobacco cessation products, as well as for pharmacists ordering and administering vaccines. In order to allow these expanded pharmacist practice protocols under Medicaid, the following changes are proposed:

- Adding "pharmacist" as a provider type eligible to enroll in the Medicaid program.
- Clarifying qualified prescriber and prescription requirements based on the pharmacist expanded practice standards.
- Amending the section related to pharmacies administering influenza vaccine to children to apply to pharmacists providing all Medicaid-covered vaccines to children and adults, pursuant to 657—Chapter 39 and the statewide protocols. The rule making also proposes adding Medicaid verification and reporting requirements. The proposed changes would enable pharmacists to take advantage of the expanded practice standards while clarifying the Medicaid verification and reporting requirements for vaccines.
- Amending the section related to basis of reimbursement for vaccines related to pharmacists. All billing and reimbursement of vaccines, regardless of provider type, would be through the Healthcare Common Procedure Coding System (HCPCS) to ensure consistency among providers as well as a coordinated Medicaid immunization record for the member.

# Fiscal Impact

To the extent that naloxone and NRT are currently being provided to Medicaid members based on a currently authorized prescriber prescription, the proposed amendments would create a different access point to the products. If a Medicaid member is not currently accessing these products through a currently authorized Medicaid provider, the proposed amendments could increase the number of prescriptions for these categories of drugs, resulting in an increase in expenditures. The extent of this potential fiscal impact cannot be determined. To the extent pharmacists are currently administering vaccines dispensed through pharmacy point of sale, there could be two potential fiscal impacts depending on the route of vaccine administration.

a. There could potentially be savings related to the difference in the current dispensing fee (\$10.07) paid under pharmacy policy and the transition to the reimbursement of the 90471 (percutaneous, intradermal, subcutaneous or intramuscular injections) administration fee (\$5.09) under medical policy.

b. There could be an increased cost related to the difference in the current dispensing fee (\$10.07) paid under pharmacy policy and the transition to the reimbursement of the 90473 (intranasal or oral route) administration fee (\$12.88) under medical policy.

Additionally, there is a potential for an increase in the number of vaccines billed by the pharmacy with these proposed changes, which could lead to an increase in total vaccine expenditures (product plus administration cost). The extent of this potential fiscal impact cannot be determined.

## Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

## Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to rule 441—1.8(17A,217).

## Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on March 31, 2020. Comments should be directed to:

Nancy Freudenberg
Department of Human Services
Hoover State Office Building, Fifth Floor
1305 East Walnut Street
Des Moines, Iowa 50319-0114
Email: appeals@dhs.state.ia.us

# Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

## Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Adopt the following **new** rule 441—77.57(249A):

**441**—77.57(249A) Pharmacists. An authorized pharmacist licensed to practice in the state of Iowa is eligible to participate in the program.

This rule is intended to implement Iowa Code section 249A.4.

ITEM 2. Amend subrule 78.2(1) as follows:

78.2(1) Qualified prescriber. All drugs are covered only if prescribed or ordered by a legally qualified practitioner an Iowa Medicaid-enrolled practitioner licensed or registered to prescribe as specified in Iowa Code section 155A.3(38). Pursuant to Public Law 111-148, Section 6401, any

practitioner prescribing drugs must be enrolled with the Iowa Medicaid enterprise in order for such prescribed drugs to be eligible for payment.

- ITEM 3. Amend subrule 78.2(2) as follows:
- **78.2(2)** Prescription required. As a condition of payment for all drugs, including "nonprescription" or "over-the-counter" drugs that may otherwise be dispensed without a prescription or drug order, a prescription or drug order shall be transmitted as specified in Iowa Code sections 124.308, 155A.3 and 155A.27 by the practitioner to the pharmacy, subject to the provisions of Iowa Code section 155A.29 regarding refills. All prescriptions or drug orders shall be available for audit by the department.
  - ITEM 4. Rescind rule 441—78.42(249A) and adopt the following **new** rule in lieu thereof:
- **441—78.42(249A) Pharmacists providing covered vaccines.** When the authorized pharmacist providing the vaccine meets all Iowa board of pharmacy expanded practice standards and Medicaid requirements, payment will be made for the following:
- **78.42(1)** Vaccines administered to children. Payment will be made to an enrolled provider for an administration fee for vaccines available through the Vaccines for Children (VFC) program administered by the department of public health if the provider is enrolled in the VFC program. Payment will be made for the vaccine cost only if the VFC program stock has been depleted.
- **78.42(2)** *Vaccines administered to adults.* Payment will be made to an enrolled provider for an administration fee and vaccine cost.
- **78.42(3)** Verification and reporting. Prior to the ordering and administration of an immunization pursuant to statewide protocol, the authorized pharmacist shall consult and review the Iowa Immunization Registry Information System (IRIS) or Iowa Health Information Network (IHIN). Within 30 calendar days following administration of any vaccine, the pharmacist shall report such administration to the patient's primary health care provider, primary physician, and IRIS or IHIN. If a patient does not have a primary health care provider, the pharmacist shall provide the patient with a written record of the vaccine administered to the patient and shall advise the patient to consult a physician.

This rule is intended to implement Iowa Code section 249A.4.

ITEM 5. Amend subrule **79.1(2)**, provider category of "Pharmacy administration of influenza vaccine to children," as follows:

Pharmacy Pharmacist vaccine administration of influenza vaccine to children

Physician fee schedule for immunization administration

Fee schedule in effect 6/30/13 plus 1%.

ITEM 6. Amend paragraph 79.1(8)"a," introductory paragraph, as follows:

- a. Except as provided below in paragraphs 79.1(8)"d" through "i," "h," all providers are reimbursed for covered drugs as follows:
  - ITEM 7. Rescind paragraph 79.1(8)"i."
  - ITEM 8. Reletter paragraphs **79.1(8)**"i" to "l" as **79.1(8)**"i" to "k."